REMARKS

Claims 29-54 are pending in the subject application. Applicant has amended claims 29, 32, 35, 36, 39, 41, 42, 46, 48, 49, 52 and 54 and cancelled claim 43 without disclaimer or prejudice. Claims 34-35, 40-41, 47-48 and 53-54 have previously been withdrawn by the Examiner. Accordingly, claims 29-42 and 44-54 are currently pending.

Support for amended claim 29 may be found in the specification, *inter alia*, on page 10, at lines 22-26 and on page 20, at lines 7-13 and from page 20, line 20 to page 21, line 3. Support for amended claim 36 may be found in the specification, *inter alia*, from page 20, line 20 to page 21, line 3 and on page 21, at lines 11-21. Support for amended claim 42 may be found in the specification, *inter alia*, from page 17, line 20 to page 18, line 8; from page 20, line 20 to page 21, line 3 and on page 21, at lines 11-21. Finally, amendments to claims 29, 32, 35, 36, 39, 41, 42, 46, 48, 49, 52 and 54 address minor issues of grammar, punctuation and the like.

The Withdrawal of Claims 34-35, 40-41, 47-48 and 53-54 Is Improper

In the March 3, 2006 Office Action, the Examiner required that applicant elect a species with respect to the R moiety of the xenobiotic fatty acid compounds defined by the formula R-COOH. In response, applicant elected the species of 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid. However, the election of this species does not justify withdrawal of claims to non-elected species encompassed within the currently pending elected and examined generic claims, i.e. claims 29, 36, 42 and 49.

Further, the Examiner stated on page 5 of the June 20, 2006 Office Action that "Applicant's traversal regarding the present

requirement for restriction among the inventions designated as Groups I-IV has been carefully considered and is persuasive." The Examiner further stated "In light of such, the requirement for election has been hereby **withdrawn** and the inventions of Groups I-IV will be examined together."

In view of the foregoing, applicant respectfully requests that withdrawn claims 34, 35, 40, 41, 47, 48, 53 and 54 be examined together with the currently pending claims, including the independent claims from which these claims depend.

A. Claims 49-52

Claims 49-52 concern a method for increasing plasma levels of HDL cholesterol in a human subject.

1. Rejection under 35 U.S.C. §103(a)

In the February 23, 2007 Final Office Action, the Examiner withdrew the rejection of claims 49-52 under 35 U.S.C. §103(a) because Bar-Tana et al. (1990) states that the cholesterol content of HDL remained essentially unaffected in the normal rate and that the 70-90% decrease in plasma cholesterol in the nephrotic rat was in plasma nonHDL-cholesterol. The Examiner noted on pages 3 and 5 of the February 23, 2007 Final Office Action that "this is an insufficient teaching to render the presently claimed method to increasing plasma levels of HDL cholesterol...obvious in view of Bar-Tana."

2. Rejections Under Obviousness-Type Double Patenting

a. Provisional Rejection

On page 9 of the February 23, 2007 Final Office Action, the Examiner withdrew the rejection of claims 49-52 for alleged obviousness-type double patenting over claims 29-24 of U.S. Patent Application Serial No. 10/735,452 because the '452 application is no longer pending and has been abandoned.

b. Non-Provisional Rejection

On page 9 of the February 23, 2007 Final Office Action, the Examiner rejected 49-52 on the ground of obviousness-type double patenting as allegedly unpatentable over claims 5 and 19 of U.S. Patent No. 4,689,344 in view of Bara-Tana et al (1990). The Examiner asserted that these issued claims and claims 36-39, 42-46 and 49-52 of the present application are not patentably distinct because the patented claims anticipate or would have rendered obvious the subject matter of these claims, referring also to page 13 of the June 20, 2006 Office Action, where as in the February 23, 2007 Final Office Action the Examiner did not distinguish between claims 36-39, 42-46 or 49-52.

In response, applicant notes that claims 5 and 19 of the '344 patent relate to "reducing serum cholesterol" not increasing plasma levels of HDL cholesterol. Therefore claims 5 and 19 of the '344 patent do not explicitly anticipate claims 49-52, as amended.

Applicant also maintains that claims 5 and 19 of the '344 patent do not inherently anticipate claims 49-52, as amended, because reducing serum cholesterol in a patient in need thereof does not necessarily or inevitably involve increasing plasma levels of HDL cholesterol in such a patient in need of reduced serum cholesterol. In fact, Bar-Tana et al. (1990) discloses that reducing serum cholesterol is not accompanied by an increase in plasma levels of HDL cholesterol. On page 159, Bar-Tana et al. states "The triacylglycerol and cholesterol content of chylomicrons and VLDL is decreased, while the cholesterol content of HDL remains essentially unaffected.." (first paragraph, emphasis added). Bar-Tana et al. further states "The reduced LDL reflects the decreased plasma content of the VLDL precursor, and

the HDL fraction remains relatively unaffected." (page 159, third full paragraph).

Finally, applicant maintains that claims 5 and 19 of the '344 patent do not render obvious claims 49-52, as amended, in view of Bar-Tana et al. (1990). As noted above in relation to the now withdrawn rejection under 35 U.S.C. §103(a) the Examiner has acknowledged that Bar-Tana et al. (1990) does not render obvious a method of increasing plasma levels of HDL cholesterol.

Accordingly, applicant respectfully requests that on the basis of the preceding the Examiner reconsider and withdraw the rejection of claims 49-52, as amended, (with claims 53 and 54 being rejoined) on the ground of obviousness-type double patenting.

B. Claims 36-39

Claims 36-39, as amended, concern a method of treating dyslipoproteinemia wherein the treatment is accompanied by an increase in plasma levels of HDL cholesterol.

1. Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 36-39 under 35 U.S.C. §103(a) as allegedly obvious over Bar-Tana et al. in view of Hertz et al. and Ferrannini et al.

In response, applicant maintains that Bar-Tana et al. does not disclose or render obvious a method of treatind dyslipoproteinemia in a human subject wherein the treatment dylipoproteinemia is accompanied by an increase in plasma HDL-cholesterol levels as recited in amended claims 36-39.

As noted above, the Examiner has already acknowledged that Bar-Tana et al. (1990) does not render obvious a method involving increasing plasma HDL cholesterol. Therefore, no combination of

Bar-Tana et al. (1990) with Hertz et al. and Ferrannini et al. would render obvious the subject matter of amended claims 36-39.

Furthermore, the nephrotic rat model disclosed by Bar-Tana et al. (1990) is not a model of dyslipoproteinemia. On page 10 of the subject application, dyslipoproteinemia is characterized as involving "combined hypercholesterolemia, hypertrigylcerdiemia, low HDL-cholesterol" (emphasis added). On page 159, Bar-Tana et al. (1990) states "The hyperlipaemic profile induced by puromycin aminonucleoside in nephrotic rats (~2000 mg % plasma triglycerides, ~400 mg % plasma cholesterol)..." (emphasis added). Thus, the nephrotic rats disclosed in Bar-Tana et al. (1990) do not have low HDL-cholesterol and therefore are not a model for dyslipoproteinemia. Further, as noted above, Bar-Tana et al. (1990) teach that the treatment of hyperlipaemic nephrotic rats with MEDICA-16 fails to affect HDL-cholesterol, and therefore certainly do not suggest or render obvious treating dyslipoproteinemia while increasing plasma levels of HDL cholesterol.

Finally, applicant maintains the argument made on pages 9-15 of the response filed November 20, 2006 to the June 20, 2006 Office Action regarding the use of the nephrotic rat as a model of dyslipoproteinemia. Applicant does not repeat this argument here but incorporates that argument by reference into the present response. Applicant notes that the references cited in that argument were discussed but complete copies were not submitted. Applicant now attaches copies of these references as **Exhibits B-H** hereto.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §103(a) of claims 36-39, as amended.

2. Rejections Under Obviousness-Type Double Patenting

a. Provisional Rejections

Applicant notes that on page 9 of the February 23, 2007 Final Office Action, the Examiner withdrew the rejection of claims 36-39 on the basis of obviousness-type double patenting over claims 29-24 of U.S. Serial No. 10/735,452.

b. Non-Provisional Rejections

On page 9 of the February 23, 2007 Final Office Action, the Examiner rejected claims 36-39 on the basis of obviousness-type double patenting as allegedly unpatentable over claims 5 and 19 of U.S. Patent No. 4,689,344 in view of Bara-Tana et al (1990). The Examiner asserted that claims 5 and 19 of the '344 patent and claims 36-39 of the present application are not patentably distinct because the patented claims anticipate or would have rendered obvious the subject matter of these claims, referring also to page 13 of the June 20, 2006 Office Action, whereas in the February 23, 2007 Final Office Action the Examiner did not distinguish between claims 36-39, 42-46 or 49-52.

In response, applicant notes that claims 5 and 19 of the '344 patent relate to "reducing serum cholesterol" not a method of treating dyslipoproteinemia wherein the treatment is accompanied by increasing plasma levels of HDL cholesterol. Therefore, claims 5 and 19 of the '344 patent do not explicitly anticipate claims 36-39, as amended.

Applicant also maintains that claims 5 and 19 of the '344 patent do not inherently anticipate claims 36-39, as amended, because reducing serum cholesterol in a patient in need thereof does not necessarily or inevitably involve treating dyslipoproteinemia wherein the treatment is accompanied by an increase in plasma HDL cholesterol levels. As stated above, Bar-Tana et al. (1990) shows

that reducing serum cholesterol is not accompanied by an increase in plasma levels of HDL cholesterol.

Finally, applicant maintains that claims 5 and 19 of the '344 patent do not render obvious claims 36-39, as amended, in view of Bar-Tana et al. (1990). As noted above in relation to the now withdrawn rejection under 35 U.S.C. §130(a) the Examiner has acknowledged that Bar-Tana et al. (1990) do not render obvious a method of increasing plasma levels of HDL cholesterol.

Accordingly, applicant respectfully requests that on the basis of the preceding the Examiner reconsider and withdraw the rejection of claims 36-39, as amended (with claims 40 and 41 being rejoined) on the ground of obviousness-type double patenting.

C. Claims 42-46

Claims 42-46 as amended relate to a method of lowering plasma levels of triglycerides accompanied by an increase in plasma levels of HDL cholesterol.

1. Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 42-46 under 35 U.S.C. §103(a) as allegedly obvious over Bar-Tana et al. in view of Hertz et al. and Ferrannini et al.

In response, applicant maintains that Bar-Tana et al. does not disclose or render obvious a method of lowering triglycerides in a human subject wherein the lowering of triglycerides is accompanied with an increase in plasma HDL-cholesterol levels as recited in amended claims 42-46.

As noted above, the Examiner has already acknowledged that Bar-Tana et al. (1990) does not render obvious a method involving increasing plasma HDL cholesterol. Therefore, no combination of

Bar-Tana et al. (1990) with Hertz et al. and Ferrannini et al. would render obvious the subject of amended claims 42-46.

Furthermore, applicant maintains that Bar-Tana et al. (1990) discloses that the lowering of plasma levels of triglycerides was not accompanied by an increase in HDL-cholesterol. As stated above, Bar-Tana et al. disclose a "70-90% decrease in plasma tricylglycerol and a 50-70% decrease in plasma nonHDL-cholesterol" (emphasis added, see page 159). Again, as noted above, Bar-Tana et al. teach that "the HDL fraction remains relatively unaffected." (see page 159), and therefore certainly do not teach increasing plasma levels of HDL cholesterol.

Finally, applicant maintains that the argument made on pages 9-15 of the response filed November 20, 2006 to the June 20, 2006 Office Action regarding the use of the nephrotic rat as a model for varying plasma levels of triglycerides. Applicant does not repeat that argument here but incorporates that argument by reference into the present response.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §103(a) of claims 42-46, as amended.

2. Rejections Under Obviousness-Type Double Patenting

a. Provisional Rejections

Applicant notes that on page 9 of the February 23, 2007 Final Office Action, the Examiner withdrew the rejection of claims 42-46 on the basis of obviousness-type double patenting over claims 29-24 of U.S. Patent Application No. 10/735,452.

b. Non-Provisional Rejections

On page 9 of the February 23, 2007 Final Office Action, the Examiner rejected claims 42-46 on the basis of obviousness-type

double patenting as allegedly unpatentable over claims 5 and 19 of U.S. Patent No. 4,689,344 in view of Bara-Tana et al (1990). The Examiner asserted that these issued claims and claims 36-39, 42-46 and 49-52 of the present application are not patentably distinct because the patented claims anticipate or would have rendered obvious the subject matter of these claims, referring to page 13 of the June 20, 2006 Office Action whereas in the February 23, 2007 Final Office Action the Examiner did not distinguish between claims 36-39, 42-46 or 49-52.

In response, applicant notes that claims 5 and 19 of the '344 patent relate to "reducing serum cholesterol" not increasing plasma levels of HDL cholesterol. Therefore, claims 5 and 19 of the '344 patent do not explicitly anticipate claims 42-46, as amended.

Applicant also maintains that claims 5 and 19 of the '344 patent do not inherently anticipate claims 42-46, as amended, because reducing serum cholesterol in a patient in need thereof does not necessarily or inevitably involve lowering plasma levels of triglycerides wherein the lowering of plasma levels of triglycerides is accompanied by an increase in plasma levels of HDL cholesterol. In fact, as noted above, Bar-Tana et al. (1990) discloses that reducing plasma levels of triacylglycerol in not accompanied by an increase in plasma levels of HDL cholesterol, stating on page 159, "The triacylglycerol and cholesterol content of chlyomicrons and VLDL is decreased, whole the cholesterol content of HDL remains essentially unaffected."

Finally, applicant maintains that claims 5 and 19 of the '344 patent do not render obvious claims 42-46, as amended, in view of Bar-Tana et al. (1990). As noted above in relation to the now withdrawn rejection under 35 U.S.C. §103(a), the Examiner has

acknowledged that Bar-Tana et al. (1990) does not render obvious a method of increasing plasma levels of HDL cholesterol.

Accordingly, applicant respectfully requests that on the basis of the preceding the Examiner reconsider and the withdraw rejection of claims 42-46, as amended (with claims 47 and 48 being rejoined) on the ground of obviousness-type double patenting.

D. Claims 29-33

Claims 29-33 relate to a method of treating Syndrome X wherein the treatment is accompanied by an increase in plasma levels of HDL cholesterol and Syndrome X comprises more than one of 5 enumerated conditions.

1. Rejection Under 35 U.S.C. §103(a)

In the February 23, 2007 Final Office Action, the Examiner rejected claims 29-33 under 35 U.S.C. §103(a) as allegedly obvious over Bar-Tana et al. in view of Hertz et al. and Ferrannini et al.

In response, applicant maintains that Bar-Tana et al. does not disclose or render obvious a method of treating Syndrome X in a human subject wherein Syndrome X comprises more than one of (1) dysliporoteinemia, (2) obesity, (3) impaired glucose tolerance leading to noninsulin-dependent *diabetes mellitus* (NIDDM) (4) essential hypertension or (5) thrombogenic/fibrinolytic defects and the treatment is accompanied by an increase in plasma levels of HDL cholesterol as recited in amended claims 29-33.

As noted above, the Examiner has already acknowledged that Bar-Tana et al. (1990) does not render obvious a method involving increasing plasma HDL cholesterol. Therefore, combining Bar-Tana et al. (1990) with Hertz et al. and Ferrannini et al. would not render obvious the subject of amended claims 29-33.

Finally, applicant maintains the argument made on pages 9-15 of the response filed November 20, 2006 to the June 20, 2006 Office Action regarding the use of the nephrotic rat as a model for treating Syndrome X. Applicant does not repeat that argument here but incorporates that argument by reference into the present response.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §103(a) of claims 29-33, as amended.

Rejections Under Obviousness-Type Double Patenting

Non-Provisional Rejections

On page 11 of the February 23, 2007 Final Office Action, the Examiner rejected claims 29-33 on the basis of obviousness-type double patenting as allegedly unpatentable over claims 1-3 and 8 of U.S. Patent No. 6,303,653.

Applicant maintains that the rejection over claims 1-3 and 8 of the '653 patent for obviousness-type double patenting is improper since the subject application is drawn to a species. The Examiner's argument that a species which anticipates a genus represents obviousness-type double patenting is not valid. As it is stated in M.P.E.P. §2131.02 "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The '653 patent claimed the genus, thus the '653 patent does not anticipate the now claimed species.

If the Examiner continues to maintain the rejection on the basis of obviousness-type double patenting over claims of 1-3 and 8 of the '653 patent, but claims 29-33 are otherwise allowable, applicant will consider filing a terminal disclaimer with respect to the '653 patent.

Accordingly, applicant respectfully requests that on the basis of the preceding the Examiner reconsider and withdraw the rejection of claims 29-33, as amended (with claims 34 and 35 being rejoined) on the ground of obviousness-type double patenting.

Supplemental Information Disclosure Statement

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant submits this Supplemental Information Disclosure Statement.

Specifically, applicant directs the Examiner's attention to the documents which are listed on the enclosed PTO-1449 form attached hereto as **Exhibit A** and listed hereinbelow.

1. Liu GL, et al., Comp. Biochem Physiol A 99, 223-228, (1991); **(Exhibit B)**;
2. Chapman MJ, et al., J. Lipid Res 34, 943-959, (1993); **(Exhibit C)**;
3. Sullivan MP, et al., Lab Anim Sci 43, 575-578 (1993); **(Exhibit D)**;
4. Hoang V, et al., Biochem Biophys Acta 1254, 37-44 (1995); **(Exhibit E)**;
5. Ohtani H, et al., J Lipid Res. 31, 1413-1422 (1990); **(Exhibit F)**;
6. Solymoss BC, et al., Am J Cardiol 76, 1152-1156 (1995); **(Exhibit G)**; and
7. Bar-Tana J, et al., J. Lipid Res 29, 431-441 (1988); **(Exhibit H)**.

Applicant notes that the documents in the response filed November 20, 2006 were not previously submitted. Thus, applicant requests

that the Examiner review the documents and make them of record in the subject application.

In accordance with 37 C.F.R.§1.17(p), the fee for filing this Supplemental Information Disclosure Statement is $180.00. A check including this amount is enclosed.

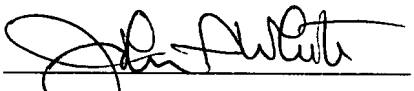
Conclusion

In view of the amendment to the claims and the remarks set forth hereinabove, applicant respectfully submits that the grounds of rejection set forth in the February 23, 2007 Final Office Action have been overcome. Therefore, applicant respectfully requests that the Examiner reconsider and withdraw these grounds of rejection, and solicit allowance of the claims now pending in the subject application, namely, amended claims 29-42 and 44-54

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the $230.00 fee for a two-month extension of time, the $405.00 fee for filing a RCE and the $180.00 fee for filing a Supplemental Information Disclosure Statement, is deemed necessary in connection with the filing of this Amendment. Accordingly, a check for $815.00 is enclosed. However, if any additional fee is required, authorization is hereby given to charge the additional amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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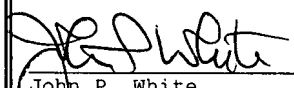

11/27/07

John P. White Date
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EXHIBIT A